Type 2 Diabetes Patients Taking Exenatide Once Weekly, a Phase 3 Investigational Diabetes Therapy, Showed Improvements in Glycemic Control, Weight

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DURATION-1 Data Presented at the 68th Annual Scientific Sessions of the American Diabetes Association

SAN FRANCISCO, June 7, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN), Eli Lilly and Company (NYSE: LLY), and Alkermes, Inc. (Nasdaq: ALKS) announced results from a 30-week study that compared the efficacy of exenatide once weekly, a long-acting release formulation of exenatide, to BYETTA® (exenatide) injection. Type 2 diabetes patients treated with exenatide once weekly, an investigational therapy, showed statistically significant improvements in A1C (-1.9%+/-0.08 (LS mean+/-SE)) and fasting plasma glucose (FPG -42+/-3 mg/dL) from baseline and compared with BYETTA (-1.5%+/-0.08, A1C and -25+/-3 mg/dL, FPG). Patients in both treatment groups also reported significant weight loss (average of 8 pounds) and 77 percent of patients treated with exenatide once weekly achieved an A1C of 7 percent or less. These findings were presented at the 68th Annual Scientific Sessions of the American Diabetes Association (ADA) in San Francisco.

BYETTA is indicated as adjunctive therapy to improve glycemic control in patients with type 2 diabetes mellitus who are taking metformin, a sulfonylurea, a thiazolidinedione, a combination of metformin and a sulfonylurea, or a combination of metformin and a thiazolidinedione but have not achieved adequate glycemic control.

"We know that a substantial number of type 2 diabetes patients are overweight, and conventional diabetes therapies, while controlling blood glucose, may have little or no beneficial impact on body weight. Importantly, the DURATION-1 results suggested the significant, beneficial impact of continuous levels of exenatide once weekly on glycemic control, and additionally, weight loss," said Daniel J. Drucker, M.D., Professor in the Division of Endocrinology, Department of Medicine, of Toronto, Director of the Banting and Best Diabetes Centre.

Study Design and Findings

The Diabetes Therapy Utilization: Researching Changes in A1C, Weight and Other Factors Through Intervention with Exenatide ONce Weekly (DURATION-1) study was a 30-week, randomized, open-label study of 295 patients with type 2 diabetes (baseline values: A1C 8.3%+/-1.0, FPG 169+/-43 mg/dL, weight 225+/-44 lbs., BMI 35+/-5.0 kg/m2, diabetes duration 6.7+/-5.0 years; mean+/-SD) who were treated with exenatide once weekly 2.0 mg or BYETTA twice daily as outlined in the approved label subcutaneously. Patients in both groups who completed the randomized portion of the study continued in an open-ended portion of the study to receive exenatide once weekly. Patients in both treatment arms showed improvements in A1C from baseline. In addition, treatment with exenatide once weekly resulted in statistically significant reductions in A1C [A1C change from baseline: 1.9%+/-0.08] compared to BYETTA [A1C change from baseline: 1.5%+/-0.08 (P=0.002)].

Seventy-seven percent of patients treated with exenatide once weekly achieved an A1C of 7 percent or less versus 61 percent for BYETTA (P=0.004). The ADA-recommended target for good glucose control is an A1C of below 7 percent. For patients entering the study with a baseline A1C of 9 percent or greater, at endpoint, 29 percent of patients treated with exenatide once weekly achieved A1C levels of 6.5 percent or less versus 13 percent for BYETTA. Both BYETTA and exenatide once weekly treatment groups showed significant glycemic improvements irrespective of baseline A1C.

Treatment with exenatide once weekly also resulted in significant lowering of FPG concentrations (reductions of -42+/-3 mg/dL, exenatide once weekly; - 25+/-3 mg/dL, BYETTA, P